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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,805	03/26/2007	Menachem Rubinstein	057878-000033-US	8352

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
08/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,805	RUBINSTEIN ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's response filed on 01 July 2010 is acknowledged and entered.

Currently, claim 31 is pending and under consideration.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 31 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Sims et al., US 2002/0098185 A1 (7/25/02, provided by applicants), and further in view of Dombroski, for the reasons of record set forth in the last Office Action mailed on 5/20/09/, and 1/21/10.

Applicants argument filed on 01 July 2010 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 3-4 of the response, the applicant argues that as evidenced previously, "Kineret should not be used with medicines called Tumor Necrosis Factor (TNF blocking agents) such as ENBREL® (etanercept), Humira TM (adalimumab), or Remicade® (infliximab)"; that TNF and IL-18 are intricately linked and that TNF blockers also block IL-18, for example, Puren et al. (J. Clin. Invest, 1998, Exhibit A) specifically shows that TNF-BP (TNF binding protein, i.e. a TNF

blocker) also inhibits IL-18 induction (see, e.g., Fig. 9), thus, contrary to the Examiner's assertion, a skilled artisan, at the time of filing the present application was aware that compounds that block TNF also block IL-18; and that knowing that TNF blockers also block IL-18, it is evident to a skilled artisan, that the warnings of simultaneous use of Kineret (anakinra) regarding combination with TNF-blockers also apply to IL-18 blockers, such as IL-18BP. This argument is not persuasive for the following reasons: first, applicants scientific interpretation of Puren's teachings is incorrect. While Puren demonstrated that TNFbp significantly attenuated IL-18 induction of TNFα mRNA in PBMC, it does not block IL-18. This effect is due to blocking the TNF activity produced in the PBMC cultures by TNFbp, and any further induction of TNF is curtailed (as TNF is known to induce TNFα) (page 717, 1st column, 2nd paragraph). Further, more importantly, *even if* "compounds that block TNF also block IL-18", it is unclear what is the logic or relevance to link the combination of Kineret and TNF inhibitor with the combination of Kineret and IL-18 inhibitor, and why the indication that Kineret should not be used with a TNF inhibitor also indicates that Kineret should not be used with a IL-18 inhibitor, as the art never teaches or suggests that blocking IL-18 by TNF inhibitors were the reason that Kineret should not be used with a TNF inhibitor. Furthermore, the true reason for that Kineret should not be used with a TNF blocking agent such as ENBREL is not because that it also blocks IL-18, rather, it is because of drug interactions, i.e., concurrent use of Kineret and ENBREL could result in increased rate of serious infection (see "Kineret" by Amgen (manufacture), 2001, page 6, under "Drug Interactions"), which is completely unrelated to TNF's ability of blocking IL-18 or IL-18 inhibitors such as IL-18BP. As such, applicants argument is confusing and unfounded.

Conclusion:

No claim is allowed.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Examiner Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Dong Jiang/
Primary Examiner, Art Unit 1646
8/6/10